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Docket No.: 1056-0136PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tomohiro MATSUSHIMA et al.

Application No.: 10/577,042

Confirmation No.: @@@

Filed: April 24, 2006

Art Unit: N/A

For: NOVEL PYRIDINE DERIVATIVE AND
PYRIMIDINE DERIVATIVE (2)

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

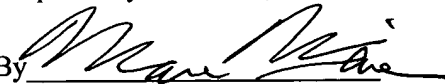
Attached is a copy of the English translation of the International Preliminary Report on Patentability (Chapter I or Chapter II) issued for the basic PCT application. Please make this of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Dated:

NOV 6 2006

Respectfully submitted,

By 

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Attachment(s)

PATENT COÖPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki
SOEI PATENT AND LAW FIRM
Bldg., 10-6
Ginza 1-chome, Chuo-ku
Tokyo 1040061
JAPON
Ginza First

| | |
|--|---|
| Date of mailing (day/month/year) 28 September 2006 (28.09.2006) | |
| Applicant's or agent's file reference FP05-0043-00 | IMPORTANT NOTIFICATION |
| International application No. PCT/JP2005/003704 | International filing date (day/month/year) 25 February 2005 (25.02.2005) |
| Applicant EISAI CO., LTD. et al | |

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Yoshiko Kuwahara |
| Facsimile No. +41 22 338 82 70 | Facsimile No. +41 22 338 82 70 |

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| | | | |
|--|--|--|------------------|
| Applicant's or agent's file reference FP05-0043-00 | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2005/003704 | International filing date (<i>day/month/year</i>) 25 February 2005 (25.02.2005) | Priority date (<i>day/month/year</i>) 27 February 2004 (27.02.2004) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant EISAI CO., LTD. | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 19 September 2006 (19.09.2006) |
| | Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int |

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

Applicant's or agent's file reference

FP05-0043-00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/003704

International filing date (day/month/year)

25.02.2005

Priority date (day/month/year)

27.02.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

EISAI CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/J

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/003704

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☒ table(s) related to the sequence listing
- b. format of material
- ☒ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/003704

| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement | | |
|--|--|-------------|-----|
| 1. Statement | | | |
| Novelty (N) | Claims | <u>1-29</u> | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | <u>1-29</u> | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | <u>1-29</u> | YES |
| | Claims | | NO |
| 2. Citations and explanations: | | | |
| <p>Document 1: WO, 2002-032872, A1 (Eisai Co., Ltd.), 25 April, 2002 (25.04.02), see for example pharmacologic test 3, embodiments 186-205 & AU, 200195986, A & NO, 200301731, A & KR, 2003040552, A & HU, 200302603, A2 & US, 2004/053908, A1 & EP, 1415987, A & CN, 1478078, A & ZA, 200303567, A</p> <p>Document 2: WO, 2003/000660, A1 (Kirin Brewery Co., LTD.), 3 January, 2003 (03.01.03), see for example embodiment 269 & CA, 2454538, A & EP, 1411046, A1 & US, 2004/242603, A1</p> <p>Document 3: WO, 2002/096361, A2 (CUI, Jingrong), 2002.12.05 & US, 2003/125370, A1 & US, 6599902, B2</p> <p>Document 4: WO, 2003/087026, A1 (F. HOFFMANN-LA ROCHE AG), 2003.10.23 & US, 2003/199691, A1 & AU, 2003240452, A1 & US, 6790852, B2 & US, 2004/214874, A1 & EP, 1499577, A1</p> <p>Claims 1-29 Inventions described in claims 1-29 are novel and inventive on account of the documents 1-4 cited in the ISR.</p> <p>Document 1 describes a pyridine or pyrimidine derivative useful as a receptor type tyrosine kinase inhibitor, an antiangiogenic agent, an antitumor agent and a cancer metastatic suppressor agent (see embodiments 186-205, etc.). Also, the document 1 can be recognized to suggest that said pyridine or pyrimidine derivative presents a hepatocyte growth factor receptor inhibitory activity (see pharmacologic test 3).</p> <p>However, document 1 does not describe nor suggest an N-atom substituted carbonyl methyl group or an N-atom substituted carbonyl group as a substituent for the carbonyl amino group on the phenyl group of the pyridine or pyrimidine derivative.</p> <p>Document 2 describes a quinoline or quinazoline derivative useful as a hepatocyte growth factor receptor inhibitor, an antiangiogenic agent, an antitumor agent and a cancer metastatic suppressor agent. Document 2 also describes an N-atom substituted carbonyl methyl group as a substituent for the carbonyl amino group on the phenyl group of the quinoline or quinazoline derivative (see for example embodiment 269).</p> <p>However, since the pyridine or pyrimidine derivative described in the document 1 and the quinoline or quinazoline derivative described in the document 2 do not have a common basic skeleton, the compounds described in claims 1-29 cannot easily be conceived from the descriptions of documents 1-2 even by a person skilled in the art.</p> <p>Documents 3-4 describe compounds presenting hepatocyte growth factor receptor inhibitory activities, but do not describe nor suggest the compounds described in claims 1-29.</p> | | | |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/003704

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

Thus, the compounds described in claims 1-29 cannot easily be conceived from the descriptions of documents 1-4 even by a person skilled in the art.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/003704

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Of the compounds described in claims 1-21 and 24-29, supported in the specification with an extent to allow a significant international search report and in the sense of PCT Article 6, and, disclosed in the sense of PCT Article 6, are limited to specific portions of the compounds described in the claims, that is, compounds of the case in which substituent R^{9b} is a group represented by $-NR^{11a}R^{11b}$.

It is added that this written opinion is based on a search performed about the compounds described in claims 1-29, without limiting the scope to those mentioned above.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/003704

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

International Patent Classification (IPC)

Int. Cl.⁷ A61P1/18, 11/00, 13/08, 13/12, 15/00, 25/00, 35/00, 43/00